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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,169	04/11/2001	Andrew G. Lee	PC10636ATMC	1529

7590 04/23/2002  
Gregg C. Benson  
Pfizer Inc.  
Patent Department, MS 4159  
Eastern Point Road  
Groton, CT 06340

EXAMINER

NGUYEN, HELEN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/23/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/833,169

Applicant(s)

LEE ET AL.

Examiner

Helen Nguyen

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 10-12 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) 37-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The claimed priority of this application to an US Provisional Application No. 60/266,387, filed on April 18, 2000, is acknowledged.

Applicant's election of Group I, claims 1-14, drawn to methods of treatment, species: formula I of claim 2, (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol of claim 4, and disorder of sexual arousal disorder, in Paper No. 5, filed February 20, 2002 is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-9 and 13-36 are canceled.

Claims 1, 11 and 12 are amended.

Claims 37-39 are considered as belonging to Group II. Therefore, they are deemed non-elected.

Claims 1-5, and 10-12 are presented for examination.

- ❖ Claimed numbers 32-34 following claim 36 have been renumbered by Legal Instrument Examiner to claimed numbers 37-39 under 37 C.F.R. 1.126.

***Specification objection***

The disclosure is objected to because of the following informalities:

On page 29 of the specification, in formula X, it appears that N is missing in pyrimidine ring.

Appropriate correction is required.

***Claim rejection- 35 USC § 112***

❖ The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, and 10-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the elected formula IA (recited in claims 2-5), and compounds recited in canceled claims 6-9, does not reasonably provide enablement for any estrogen agonists/antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. On pages 14 -26, Applicants disclose formula IA and the

compounds of canceled claims 6-9 as estrogen agonists/antagonists. No other estrogen agonists/antagonists are disclosed.

2. Claims 1-5 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for PDE<sub>v</sub> phosphodiesterase inhibitors of formulae VII-XIA, does not reasonably provide enablement for any PDE<sub>v</sub> phosphodiesterase inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. On pages 27-33, Applicants disclose formulae VII-XIA as PDE<sub>v</sub> phosphodiesterase inhibitors. No others are disclosed.

The level of predictability (a Wands factor) in chemical arts is low. Undue experimentation (a Wands factor) would, therefore, be required to determine the compounds other than those disclosed. Applicants provide no example (a Wands factor) for compounds other than those disclosed.

### ***Conclusion***

Claims 1-5 and 10-12 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen

Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen  
Patent Examiner


April 19, 2002

Application/Control Number: 09/833,169  
Art Unit: 1617

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Helen Nguyen  
Patent Examiner

April 19, 2002



EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500